

510(k) Summary**CAAS MR Flow****Release 1.0**

This summary statement complies with 21CFR, section 807.92(c).

Date summary prepared: 17-Mar-09

This premarket notification has been submitted by Pie Medical Imaging BV and covers the CAAS MR Flow software package. Pie Medical Imaging is located at:

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MAY 22 2009

The contact person is: Ms. Saskia Lloyd, Quality Assurance Officer

The trade name is: CAAS MR Flow

The common name is: Magnetic Resonance Flow analysis software

The classification name is: Image Processing System (I.I.Z), CFR 892.2050.

The above as stated in 21 CFR, part 892.1570, has been classified as regulatory Class II.

The CAAS MR Flow software package is substantially equivalent to the quantitative analysis software package CAAS MRV Version 3.0, K060941, integrating flow analysis functionality substantially equivalent to MRI Flow, Medis medical imaging systems BV, K994282.

The CAAS MR Flow is a software tool providing functionality to import and view MR quantitative flow datasets and corresponding reference images. Contours of blood in vessels and through heart valves can be delineated automatically, semi-automatically or manually. Within these contours data on flow and velocity can be derived and parameters of interest for clinical use can be calculated. All results of the analysis are available on screen as well as hardcopy, and can be saved.

The intended use of CAAS MR Flow is to enable the user to:

1. Delineate the contours of blood in vessels and through heart valves in Phase-Contrast MR images; manually, semi-automatically or automatically.
2. Derive from these images and contours quantitative cardiovascular analysis results.

The CAAS MR Flow has been designed to be used in everyday clinical practice to support clinical diagnoses, as well as for research purposes like clinical research trials.

The CAAS MR Flow is substantially equivalent to the predicate devices mentioned in this summary by using the same technological characteristics and intended use.

The CAAS MR Flow is produced under the same Quality Assurance system applicable to the development and production of products currently marketed by Pie Medical Imaging.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 22 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Saskia Lloyd
Submission Correspondent Quality Assurance Office
Pie Medical Imaging b.v.
Becanusstraat 13D, 6216 BX Maastricht
THE NETHERLANDS

Re: K090155
Trade/Device Name: CAAS MR Flow
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 23, 2009
Received: April 29, 2009

Dear Mr. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

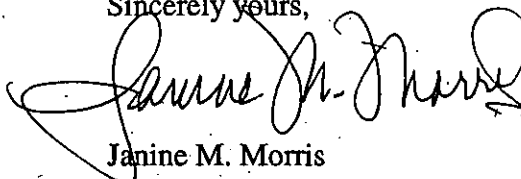
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Notification - CAAS MR Flow

INDICATION FOR USE STATEMENT

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510(k) number (if known): K090155

Device Name: CAAS MR Flow

Indications For Use:

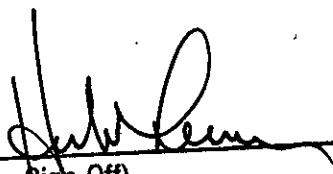
1. Delineate the contours of blood in vessels and through heart valves in Phase-Contrast MR images; manually, semi-automatically or automatically.
 2. Derive from these images and contours quantitative cardiovascular analysis results.
- The CAAS MR Flow has been designed to be used in everyday clinical practice to support clinical diagnoses, as well as for research purposes like clinical research trials.

Prescription Use ☒ OR Over-The-Counter Use ☐
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090155